IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, V. ACCORD HEALTHCARE INC., ET AL., Defendants.	C.A. No. 18-1043-KAJ

DEFENDANTS HEC PHARM CO., LTD. AND HEC PHARM USA INC.
POST-TRIAL RESPONSE BRIEF ON NON-INFRINGEMENT

Respectfully submitted,

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TABLE OF ABBREVIATIONS

Abbreviation	Exhibit No.	Description
'405 patent	JTX-001	U.S. Patent No. 9,187,405
HEC Label	PTX-310	Fingolimod
HEC		Metabolite of FTY720
Novartis		Multiple Sclerosis
ANDA		Relapse-remitting multiple Sclerosis
MS		Multiple Sclerosis
RRMS		Relapse-remitting multiple sclerosis
JSUF ¶ [X]		Joint Statement of Uncontested Facts, Dkt. [X-X], Exhibit 1 to Final Pretrial Order.
HFF ¶ [X]		HEC's Findings of Fact, Dkt. No.
SFF ¶ [X]		HEC's Supplemental Findings of Fact
SCOL ¶ [X]		HEC's Supplemental Conclusions of Law
NFF ¶ [X]		Novartis's Findings of Facts, Dkt. No. XX

Defendants HEC Pharm Co., Ltd. and HEC Pharm USA Inc. (collectively, "HEC"), pursuant to the Final Pretrial Order filed in this matter at Dkt. 715, hereby submits its Responsive Post-Trial Brief on Non-infringement.

INTRODUCTION & BACKGROUND

Novartis has not proven by a preponderance of the evidence that HEC has induced infringement of the '405 patent or contributed to infringement of it. Each of the claims of the '405 patent include a limitation that 0.5 mg fingolmod is administered daily absent an immediately preceding loading dose. Novartis chose to include this negative limitation in its claims to overcome a rejection from the prior art Kovarik reference (an MS-related study that included a loading dose), which included a loading dose. Back then, Novartis chose the scope of its claims.

Now, Novartis wants to have the Court ignore these facts and render this claim limitation irrelevant for the infringement analysis. For there to be induced infringement of a method claim in Hatch-Waxman cases, the specific intent to infringe the patent, the label must encourage, recommend, or promote infringement; put another way, it must instruct the physician to perform each limitation. Here though, there is no dispute that HEC's Label (the product by which Novartis must measure infringement against) does not expressly instruct a physician omit a loading dose from the dosing regimen. No matter, Novartis says, such a explicit statement would be "superfluous." It was not superfluous during prosecution—it was necessary to obtain the patent.

Without an explicit instruction, Novartis then argues that an implicit inference may replace the explicit one, and provide sufficient evidence of specific intent. To try to make this showing, Novartis points to the label and to documents not included in the label. The only piece of evidence in this trial that could have shown that HEC encouraged, recommended, or promoted dosing absent an immediately preceding loading dose is a document that states the maximum daily dose for

fingolimod is 0.5mg (therefore precluding a dose higher than that, which a loading dose must be). But that document is not part of the label and it is not provided to physicians; HEC cannot induce someone with a document that they do not give them. Novartis then points to warnings on the label regarding a known side effect, bradycardia, as evidence that HEC instructs a physician to administer absent an immediately preceding loading dose. But warnings are not instructions, especially where the warning of a side effect is the same type of side effect that the patient will be monitored for upon initiation of fingolimod. This warning cannot reasonably direct a physician away from a dose by saying that the risks are the same as they would encounter at the lower dose, and where the label confirms both doses are effective.

The last grasp on induced infringement is for Novartis is to try to lower the bar—instead of trying to prove that there was an explicit or implicit instruction to exclude the loading dose, Novartis mischaracterizes Federal Circuit caselaw to try to argue that all it needs to show for specific intent is that as a result of the label, at least some users will invariably infringe the claim. But the case it relies on, and cases after that, confirm that Novartis's reading is wrong. The Federal Circuit has ***always*** required more: it requires active conduct. Those facts are not in evidence here, and Novartis has failed to prove by a preponderance of the evidence that HEC induces infringement of the '405 patent.

Recognizing that it has issues with proving intent, Novartis tries to resurrect a contributory infringement claim in the PTO, but that they never raised at trial and their experts never offered on opinion on. They readily admit why they are doing so: "The standard is less than the intent required for induced infringement—contributory infringement requires only proof of a defendant's knowledge, not intent, that his activity cause infringement." (Novartis Opening Br. at 19.) But even so, Novartis still must prove each and every element required for contributory infringement

to prevail; it has not done so. In its haste, Novartis failed to even address at least one requirement and failed to even make a *prima facie* case for another.

ARGUMENT

I. NOVARTIS HAS FAILED TO PROVE THAT HEC INDUCES INFRINGEMENT.

Every claim of the '405 patent contains the same limitation that 0.5 mg fingolimod is administered daily "absent an immediately preceding loading dose regimen." (HFF 9) A loading dose is a "greater-than-normal dose that you usually use at the start of a therapy to sort of jump start the levels [of the drug] in the body." (HFF 109.) Novartis has failed to prove by a preponderance of the evidence that HEC induces physicians to perform the step of administering 0.5mg fingolimod daily absent an immediately preceding loading dose regimen. (SCOL 16.)

Inducing infringement requires proof of specific intent to encourage an infringing use. *See Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019). (SCOL 7.) Thus, the question is whether HEC's proposed label instructs users to perform the patented method. *See Sanofi v. Glenmark Pharm. Inc., USA*, 204 F. Supp. 3d 665, 673 (D. Del. 2016), *aff'd sub nom. Sanofi v. Watson Labs. Inc.*, 875 F.3d 636 (Fed. Cir. 2017). In Hatch-Waxman cases, "[t]he mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement." *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). Instead, "[t]he label must encourage, recommend, or promote infringement." *Id*. Likewise, merely describing an infringing use is not sufficient for inducement. *See id.* (SCOL 7.) As applied to the issue before the Court, that question distills to: ***Does HEC's proposed label promote, encourage, or recommend that physicians prescribe fingolimod in the absence of an immediately preceding loading dose?***

As Dr. Hoffman confirmed and Novartis readily admits, HEC's label is ***silent*** as to a loading dose. (SFF 1, 5 (Hoffman Tr. 641:16–22); Novartis Br. at 16 (admitting that HEC's label

"does not tell doctors explicitly not to use a loading dose").) Thus, it is clear that HEC's label does not affirmatively instruct physicians to omit use of a loading dose. (SFF 5 (Hoffman Tr. 567:6–12).) In the absence of an affirmative instruction in the proposed label—and in the absence of any evidence of HEC's state of mind whatsoever—Novartis tries to manufacture specific intent through other parts of the label and to portions of HEC's ANDA filings (which are not even part of the label and not provided to physicians) to try to prove the existence of an instruction to exclude use of a loading dose. These efforts fail to establish by with any evidence—much less a preponderance of the evidence—HEC's specific intent to induce infringement.

A. Novartis Failed to Prove that HEC's Label Implicitly Encourages or Instructs Physicians.

Novartis concedes as it must that HEC's label "does not tell doctors explicitly not to use a loading does," and argues instead that "the label's silence on loading doses thus must be understood to exclude a loading dose." (Novartis Br. at 16.) Novartis also points to cautions within the label to argue it constitutes implicit encouragement sufficient to carry its burden of proof establishing that HEC specifically intends to induce infringement. Both arguments lack merit.

First, the label's silence here cannot establish that the label necessarily excludes a loading dose. At the outset, Novartis attempts to claim that including an explicit instruction telling doctors to omit use of a loading dose "would be superfluous." (Novartis Br. at 16.) Yet the no loading dose negative limitation was not a superfluous addition to the asserted claims during prosecution. In fact, Novartis tried and failed during prosecution to argue that an amendment to claims with daily dosages of 0.5mg fingolimod was not necessary to overcome the prior art—but instead of sticking to that argument by continuing to traverse the rejection or by filing an appeal from the Examiner's rejections—Novartis chose to get around the rejection by amending its claims to add the negative claim limitation. (FF 18.) As Novartis admitted at the time, its amendment to add the "absent an

immediately preceding loading dose" negative claim limitation was made to "further distinguish [the] claims from the disclosure of Kovarik." (FF 18.)

At trial, when addressing whether HEC's label induced infringement of claims containing the limitation "daily dosage of 0.5mg absent the immediately preceding loading dose," Dr. Lublin cited three pieces of information: (1) Section 2.3 of the label for "Recommended Dosage"; (2) a cutout from a medication guide, which is attached to the labels and directed to patients not physicians, which states "take fingolimod capsules one time each day;" and (3) "an ANDA document that was the quality overall summary that on its face page said the maximum daily dose of fingolimod is 0.5mg." (SFF 7; (Lublin Tr. 226:25–229:9 (referencing PDX-118); PTX-273.0001 (Sept. 2014 HEC Quality Overall Summary); PTX-310.006, .0035 (Recommended Dosage Section and Medication Guide).)

Novartis defeats its own argument when it admits that it must look ***outside*** HEC's label to find an upper limit for daily dosing. Dr. Lublin identifies and relies on HEC's Quality Overall Summary which states that the maximum daily dose of fingolimod is 0.5mg. (SFF 7). In fact, ***that*** statement, if it were actually in the label, could potentially be used as evidence of encouraging or instructing a physician not to use a loading dose. ***But it is not in HEC's label.*** The Quality Overall Summary ***is not*** part of the label and it is ***not*** provided to physicians—thus it cannot induce physician infringement. (SFF 8.)

Novartis also trots out a parade-of-horribles, asserting that "drug sponsors would have to pad labels with huge lists of prohibited dosing regimens, rendering the labels unreadable" if Novartis were required to prove that a label must affirmatively encourage or instruct a physician not to use a loading dose if patent claims require omitting use of a loading dose. (Novartis Br. at 16.) But this argument is non-sensical. HEC is not arguing that the label must list all of the

prohibited dosing regimens to comply with FDA regulations for labeling. HEC is only arguing that if a patent owner seeks to maintain a decades-long monopoly on a claim it wrote—even if that claim includes a negative limitation—then the patent owner must actually be required to prove HEC's specific intent to induce infringement of claims containing that negative limitation. Novartis's parade-of-horribles only comes to pass if a patent owner obtained a patent that includes claims with a huge list of prohibited dosing regimens.

Second, Novartis argues that the warnings within the label implicitly instruct physicians not to exceed 0.5mg in a day, and therefore establish HEC's specific intent to infringe. There are two statements within the label that Novartis points to: (1) "fingolimod doses higher than 0.5 mg are associated with a greater incidence of adverse reactions without additional benefit" and (2) a risk of bradycardia. (Novartis Br. at 16.) But courts have made clear that warnings alone are not enough—and that do not rise to the level of an instruction. "There is a rather significant difference between a warning and an instruction. A warning provides information regarding a potential risk. It does not prescribe a course of action. An instruction, on the other hand, is a statement directing one to take some action, such as how to avoid a potential adverse event." *United Therapeutics Corp. v. Sandoz, Inc.*, No. 12-CV-01617, 2014 WL 4259153, at *18 (D.N.J. Aug. 29, 2014) (SCOL 8.)

Both of these statements do nothing more than provide information regarding a potential risk. With respect to the risk of bradycardia, Novartis specifically argues that "HEC's ANDA documents warn against the risk of bradycardia from an 'overdose' higher than [0.5mg]." (Novartis Br. at 16 (citing PTX-310.0006, 0008, .0020, .0021, .0033, .0035).) But, the evidence that Novartis cites does not support the inferences it makes. In particular, nothing in the cited label identifies what amount of fingolimod constitutes an "overdose." (SFF 3.) Additionally, the risk associated

with overdose (bradycardia) is the exact same risk associated with taking 0.5mg daily dose. (SFF 3 (*Compare* PTX-310.0008 ("Because of a risk for bradyarrhythmia and AV blocks, patients should be monitored during fingolimod treatment initiation [*see Dosage and Administration (2.4)]*") *with* PTX-310.0020 ("Fingolimod can induce bradycardia as well as AV conduction blocks (including complete AV block) . . . In case of fingolimod overdosage, observe patients overnight with continuous ECG monitoring in a medical facility, and obtain regular measurements of blood pressure *[see Dosage and Administration (2.4)]*.").) The risk to patients is not avoided by a physician prescribing only 0.5mg.

Thus, under proper analysis of the case law, Novartis has not established by a preponderance of the evidence that HEC specifically intends to induce infringement because it has not proven that HEC's label encourages, recommends, or promotes affirmatively excluding a loading dose. (SFF 5; SCOL 16.)

B. Novartis Cannot Use Misrepresented Case Law to Infer Intent Once it Fails to Prove Its Case Under the Correct Case law.

Without evidence that HEC's label did not affirmatively or implicitly instruct physicians to omit use of a loading dose, Novartis attempts to move the goal posts. Relying heavily on *AstraZeneca LP v. Apotex, Inc.*, Novartis claims that a label that "will cause at least some users" to infringe is all that is required to "infer . . . an affirmative intent to infringe the patent." (Novartis Br. at 14 (quoting *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059-60 (Fed. Cir. 2010).) Novartis then string cites several other cases (most of which cite to *AstraZeneca*) for the same proposition—i.e., that the only thing Novartis needs to show to prove HEC's specific intent to induce is that, as a result of the label at least some users will infringe. But Novartis wholly mischaracterizes *AstraZeneca*. Even more troubling is that *Astrazeneca* itself and other Federal

Circuit cases have made clear that the interpretation Novartis presented to the Court is at best incomplete and at worst, misleading.

First, *AstraZeneca* was not a Hatch-Waxman case brought pursuant to § 271(e) (where infringement is the filing of the ANDA as an artificial act of infringement), but instead it was brought as a declaratory judgment seeking a finding of infringement pursuant to § 271 (a)-(c) (direct, induced, and contributory infringement). *See AstraZeneca*, 633 F.3d at 1047 (FDA approved Apotex's ANDA on March 30, 2009 and AstraZeneca filed a declaratory judgment act the following day). More importantly—and contrary to Novartis's argument— *AstraZeneca* did not find specific intent to infringe solely because "the label will cause at least some users" to infringe the patent. *Id.* at 1059–60. Far from it. *AstraZeneca* makes it crystal clear that more is required, yet Novartis left that analysis out:

> "[T]he district court found that Apotex had the requisite specific intent to induce infringement because Apotex included instructions in its proposed label that will cause at least some users to infringe the asserted method claims. ***The district court also found that, despite being aware of the infringement problem presented by the proposed label, Apotex nonetheless proceeded with its plans to distribute its generic drug product. This conduct, not merely the planned distribution of the generic drug, formed the basis of the district court's specific intent finding.***

Id. (emphasis added). With respect to the infringement problem, the court noted that there was evidence in the record that "Apotex 'was aware of and certainly concerned about the potential infringement problem proposed by its label,' but nevertheless decided to proceed." *Id.* at 1059. The problem for Apotex in *AstraZeneca* is that Apotex had already attempted to carve out infringing uses and the FDA rejected that attempt in a letter that "explicitly stated (and therefore put Apotex on notice) that" a certain portion of the language in the label may involve once-daily dosing, which Apotex attempted to carve out. *See id.* at 1058. Novartis's brief ignores these critical facts—and importantly, Novartis's trial presentation did not include any evidence of HEC's

conduct or intent with respect to HEC's proposed labeling process—and so Novartis had no evidence to cite in its post-trial brief establishing HEC's specific intent to induce infringement. (SFF 7–10; Novartis Opening Br. at 14–16.)

Further, while Novartis selectively acknowledged that HEC submitted a Paragraph IV letter challenging invalidity, it neglected to disclose to this Court that HEC's Paragraph IV letter also included and disclosed HEC's rationale for why it believed that it did not infringe the '405 patent, because HEC's label does not include any instruction or encouragement to physicians directed to the negative claim limitation "absent an immediately preceding loading dose." (*See* Novartis Br. at 19 (citing JSUF ¶ 21 which establishes that HEC's Paragraph IV letter contended that HEC does not infringe).) Like in traditional patent infringement cases, in Hatch-Waxman litigation, a reasonable, good-faith belief in noninfringement can negate the specific intent required for induced infringement and applies where such a belief is based on a reasonable reading of the patent claims, even if that reading is later found to be incorrect. *In re Biogen '755 Patent Litig.*, 335 F. Supp. 3d 688, 714 (D.N.J. 2018). HEC's Paragraph IV Letter evidenced HEC's reasonable, good-faith belief that it was not inducing any infringement. (JSUF ¶ 21.)

Novartis's interpretation is also inexplicable in the face of the Federal Circuit expressly rejecting the same argument in *Grunenthal GMBH v. Alkem Labs., Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019)—a case Novartis cites in its brief. Addressing patent owners that relied heavily on the *AstraZeneca*, the *Grunenthal* court corrected their readings (calling it inapposite) because *AstraZeneca* "held that specific intent could be inferred because the defendant proceeded with a plan to distribute the generic drug knowing that its label posed infringement problems. In addition, the instructions in the DOSAGE AND ADMINISTRATION section of the label would inevitably lead some consumers to practice the claimed method." *Grunenthal*, 919 F.3d at 1340. The

defendants in *Grunenthal* (like HEC) were situated different than those in *AstraZeneca* because the patent owner "point[ed] only to the indications of the proposed labels as grounds for of inducement, which, as explained above, do not implicitly or explicitly encourage or instruct users" to take action that would inevitably lead to infringement. *See id.* The same is true of HEC and this renders *AstraZeneca* inapposite to the facts in this case. Moreover, Novartis presented no testimonial evidence from any HEC witness during trial—thus Novartis has nothing like the specific intent evidence presented in *AstraZeneca*.

Novartis also cites *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, C.A. No. 1:14-cv-1043-RGA, 2017 WL 1278672 (D. Del. Apr. 3, 2017). (Novartis Opening Br. at 14.) In a case Novartis was involved in, it summarized the holding as follows: "In Hatch-Waxman cases alleging that a proposed drug label will induce infringement by physicians . . . a [proposed] package insert containing directives that will 'inevitably lead some consumers to practice the claimed method' provides sufficient evidence for a finding of specific intent." (Novartis Br. at 14 (citing *Novartis*, 2017 WL 1278672, at *3) What Novartis's ellipses omits is "The label must encourage, recommend, or promote infringement. The mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement. Rather, ***specific intent and action to induce infringement must be proven***." *Id.* (internal citations and quotations omitted). In addition, "vague label language cannot be combined with speculation about how physicians may act to find inducement," because that would convert "that which [the Federal Circuit] ha[s] held is legally irrelevant—mere knowledge of infringing uses—into induced infringement." *Takeda*, 785 F.3d at 631–32 (internal citations omitted). (SCOL 9.)

Novartis string-cites several other cases on the same topic, yet none of them change the proper reading of *AstraZeneca* and none of them cure Novartis's failure to prove that HEC had the

specific intent necessary for induced infringement. (SCOL 16.) Finally, Novartis cites to *Forest Labs. Holdings Ltd. v. Mylan Inc.*, 206 F. Supp. 3d 957 (D. Del. 2016) to argue that its interpretation of *AstraZeneca* applies equally to cases with negative limitations. (Novartis Br. at 17-18 (citing *Forest Labs. Holdings Ltd. v. Mylan Inc.*, 206 F. Supp. 3d 957 (D. Del. 2016).) According to Novartis, the court found induced infringement based on a warning that warned against co-administration with amino acids (the negative limitation), "just as HEC's label warns against doses higher than 0.5 mg daily." (Novartis Opening Br. at 18 (citing *Forest Labs.*, 206 F. Supp. 3d at 975-76).) But the warnings in *Forest Labs* were far more stark, and were akin to an actual instruction, because the evidence presented established that the co-administration "could lead to potentially life-threatening side effects and such combinations could be potentially very dangerous for fibromyalgia patients," and the claimed method was for treatment of fibromyalgia. *Forest Labs.*, 206 F. Supp. 3d at 975. *Forest Labs* is thus not a comparable case and cannot overcome Novartis's utter lack of evidence directed to HEC's specific intent.

In sum, Novartis has failed to prove that HEC explicitly or implicitly encouraged, recommended, or promoted to physicians the negative limitation of excluding a loading dose. Likewise, Novartis cannot be permitted to rewrite inducement law to cure its failure of proof.

II. NOVARTIS HAS FAILED TO PROVE CONTRIBUTORY INFRINGEMENT

Novartis apparently realized post-trial that it may not be able to establish the intent required for induced infringement, so it appended an attempt to establish HEC's contributory infringement to the end of its brief in less than four pages—even though Novartis never even mentioned it during trial. It should thus be no surprise that Novartis failed to carry its burden for establishing contributory infringement. To carry its trial burden, Novartis was required to establish by a preponderance of the evidence presented at trial each of the following: an offer to sell, sale, or

import a material for use in practicing a patented process; a component or material for use in a patented process constituting a material part of the invention; knowledge by the defendant that the component is especially made or especially adapted for use in an infringement of such patents, and not a staple article suitable for substantial non-infringing use. *See, e.g.*, 35 U.S.C. § 271(c); *Forest Labs.*, 206 F. Supp. 3d at 974. (SCOL 17.) Defendant "must know that the combination for which his component was especially designed was both patented and infringing." *Global–Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011). (SCOL 17.) Importantly, the patent owner bears the burden of initially proving that there are no substantial noninfringing uses for the products. *Grunenthal*, 919 F.3d at 1340 (citing 35 U.S.C. § 271(c)). (SCOL 18.) "A noninfringing use is substantial when it is 'not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.'" *Id.* (internal quotations omitted) (affirming district court finding of substantial non-infringing use). (SCOL 18.)

Dr. Lublin, Novartis's expert on infringement, never mentioned contributory infringement—nor did he testify to the absence of substantial non-infringing use. (*See* SFF 11.) And he would not have been permitted to so testify if he had tried. In Dr. Lublin's infringement expert report, to which he is cabined, he summarized his infringement opinions as follows: "As set forth below, defendants' ANDAs infringe the claims of the 405 Patent, as those claims have been construed by the Court. The labels of defendants' ANDA products instruct physicians to perform every step in the methods claimed by the 405 Patent. A physician would follow the label, which sets out a complete dosing regimen, and would perform the dosing as the label instructed and for the purpose set out the claim preambles." (Ex. A to Decl. of Steven J. Udick, First Expert Report of Dr. Lublin, ¶ 9.) Other than an incomplete recitation of the legal principles for contributory infringement (*see* ¶ 20), Dr. Lublin's report disclosed no opinion directed to any

required element for contributory infringement. Dr. Lublin's Supplemental Expert Report on Infringement does not expand the scope of his opinions at all. (Ex. B to Decl. of Steven J. Udick, Supplemental Expert Report of Dr. Lublin.)

Even during closing, Novartis's counsel infringement presentation referenced ***only*** the standard for induced infringement ("whether the label instructs users to perform the patented method"). (Novartis Closing Tr. 948:17-950:16.) Thus, given it was Novartis's burden to establish HEC's contributory infringement, Novartis's brief misses the mark when it argues that "HEC has offered no separate defense to [contributory infringement]—HEC did not even mention contributory infringement in closing argument." (Novartis Br. 18-19.) Novartis itself failed to raise this claim even once during the entire trial.

For these reasons, it is no surprise that Novartis failed to prove its contributory infringement claim. First, Novartis failed to offer any evidence at trial that there are no substantial noninfringing uses for the products—and it completely failed to address, let alone offer evidence establishing that HEC knew its ANDA product is especially made or especially adapted for an infringing use, and not a staple article suitable for substantial noninfringing use. (SCOL 17, 19, 20.)

A. Novartis Has Failed to Show a Prima Facie Case of No Substantial Non-infringing Uses.

Turning first to Novartis's failure to make out a *prima facie* case of no substantial non-infringing use, Novartis attempts to proffer improper evidence to establish its prima facie case of no substantial noninfringing use. For example, Novartis argued that it "showed at trial that **HEC's label** will contribute to infringing claims 1-6 of the 405 Patent under 271(c)." (Novartis Br. at 18; emphasis added.) But HEC's ***label*** does not—and cannot by itself—establish that HEC's ANDA product is not a staple article suitable for substantial non-infringing use, as 271(c) requires.

Moreover, Novartis only cites to statements made by HEC's counsel to support its position that a use involving a loading dose would be off-label (Novartis Br. at 20). But this is not evidence and the Court cannot properly consider it as such. *See Finjan, Inc. v. Symantec Corp.*, No. 10-CV-593 (GMS), 2013 WL 5302560, at *25 (D. Del. Sept. 19, 2013), *aff'd*, 577 F. App'x 999 (Fed. Cir. 2014) (rejecting argument that an alleged "admission" made in closing argument is properly considered evidence and noting that "[i]t is well established that attorney argument does not constitute evidence.") (SCOL 4.) Novartis cites to no evidence in the contributory infringement portion of its brief to support this claim. (*See* Novartis Br. at 18–22.)

The legal test for a substantial noninfringing use is a use that is "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *See Grunenthal*, 919 F.3d at 1340 (citing 35 U.S.C. § 271(c)). (SCOL 18.) Dr. Lublin testified on cross-examination that, with respect to delivering a loading dose early in the treatment, that for a chronic disease like MS it would "usually not" occur, that there are "unusual circumstances where you'll do it"—but he then went on to correct himself and admitted that, "***Actually***, ***you do it acutely with relapses***." (SFF 13 (Lublin 290:6-20).)

Further, use of a non-infringing loading dose in this instance is not experimental and not off-lable. The label identifies studies that included a dose of 1.25mg and that dose provided similar levels of efficacy as the 0.5mg dose. (SFF 4 (PTX-310.0027-.0029).) Thus, a doctor reviewing the label would know that those doses were involved in several clinical studies. (SFF 4.) Additionally, Dr. Jusko testified during trial (in an effort to support validity in the face of Kappos 2006) that "fingolimod has a very long half-life" and that "very typically drugs with long half lives, because they take so long to come to steady state, to an equilibrium, they're often given with loading doses." (SFF 14 (Jusko Tr. 897:14-898:4).)

These admissions make clear that, if Novartis is to be credited with its positions about the potential use of loading doses in the context of Kappos 2006, then it cannot also claim that the use of a loading dose (e.g. 1.25mg) is so "unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental" that it is not a substantial non-infringing use. *See Grunenthal*, 919 F.3d at 1340. (SCOL 18.)

B. Novartis Failed to Present Evidence that HEC Knew its' ANDA Product is Especially Made or Adapted for Infringing Use, and Not a Staple Article Suitable for Substantial Noninfringing Use.

As shown above, one element of contributory infringement is that the patent owner must prove knowledge by the defendant that the component is ***especially made or especially adapted for an infringing use, and not a staple article suitable for substantial noninfringing use***. *See, e.g.*, 35 U.S.C. § 271(c); *Forest Labs.*, 206 F. Supp. 3d at 974. Novartis utterly failed to even discuss this required element during trial or in its post-trial briefing. (Novartis Br., *passim*.)

Novartis asserts that "HEC indisputably knew about the 405 Patent upon providing a Paragraph IV letter to the FDA. That letter expressly attacked the Patent as supposedly invalid." (JSUF ¶ 21.) However, knowledge of the patent is not enough—Novartis must also prove based on a preponderance of evidence that HEC knew its ANDA product is especially made or especially adapted for an infringing use, and not a staple article suitable for substantial noninfringing use. Novartis's brief is worse than silent—it is misleading with respect to carrying its burden on this dispositive element of its claim—because the Pretrial Order stipulated fact it cites actually stipulates that HEC's ANDA included a certification that, in HEC's opinion, "the '405 Patent is invalid, unenforceable, **and/or will not be infringed by the commercial manufacture, use, and sale of HEC's ANDA Product**." (JSUF ¶ 21.) Thus, the only "evidence" Novartis cites that could even arguable establish this element of its contributory infringement claim in fact establishes that HEC has always maintained that its ANDA product does not infringe or contribute to the

infringement of Novartis's patent—and in view of Novartis's failure of proof this pretrial stipulation rebuts any inference that HEC had the knowledge required for contributory infringement.

Novartis did not have an expert—or any other trial witness—that offered an opinion on contributory infringement, or that otherwise established HEC's contributory infringement. Novartis thus failed to present *any* evidence establishing—or even addressing—this independent requirement to prove that HEC knew its ANDA product is especially made or especially adapted for an infringing use, and not a staple article suitable for substantial noninfringing use. This failure of proof precludes a finding of contributory infringement by HEC.

CONCLUSION

For all of the foregoing reasons, Novartis's asserted claims are invalid.

Respectfully submitted,

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